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Date : May 17, 2004

From : John B. Alexander, Ph.D.      Fax : (617) 439-4170      Direct : (617) 517-5555

To : Group 1600  
U.S. Trademark & Patent Office      Fax : (703) 872-9306      Direct :

Pages : 10

(including cover sheet)

If you received a partial delivery, please call Michelle P. Chicos at (617) 517-5551.

Re :

Enclosed please find a Response to Restriction Requirement in connection with U.S. Serial No. 09/913,669.

Please do not hesitate to contact me if you have any questions, or if I can be of any further assistance at this time.

Best Regards,

John B. Alexander, Ph.D.

JBA:mpc

Fax

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PAGE 1/10 \* RCVD AT 5/17/2004 4:20:22 PM [Eastern Daylight Time] \* SVR:USPTO-EFXXRF-1/3 \* DNIS:8729306 \* CSID:617 439 4170 \* DURATION (mm-ss):02:46

Practitioner's Docket No. 56238-DIV(71526)**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: M. Sakanaka, et al.  
Serial No.: 09/913,669  
Filed: August 16, 2001  
For: CEREbroVASCULAR REGENERATION/ RECONSTRUCTION-  
PROMOTING AGENTS AND SECONDARY NERVOUS TISSUE  
DEGENERATION-INHIIBITING AGENTS COMPRISING GINSENOside RB1

GROUP: 1623  
EXAMINER: D. Khare

**Mail Stop: Amendment**  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, VA 22313-1450**

**AMENDMENT TRANSMITTAL**

1. Transmitted herewith is a Request for Reconsideration for this application.

**STATUS**

2. Applicant is  
☐ a small entity. A statement:  
☐ is attached.  
☐ was already filed.  
☒ other than a small entity.

**EXTENSION OF TERM**

*NOTE: "Extension of Time in Patent Cases (Supplement Amendments) - If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period."*

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**CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. SECTION 1.8(a))**

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

- ☐ deposited with the United States Postal Service with sufficient postage by First Class Mail in an envelope addressed to the Commissioner for Patents, Alexandria, VA 22313-1450.

**FACSIMILE**

- ☒ transmitted by facsimile to the Patent and Trademark Office, Group 1623 at (703) 872-9306.

Signature



Michelle P. Chicos

(type or print name of person certifying)

Date May 17, 2004

(Amendment Transmittal--page 1 of 4)

*If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of December 10, 1985 (1061 O.G. 34-35).*

NOTE: See 37 C.F.R. Section 1.645 for extensions of time in interference proceedings, and 37 C.F.R. Section 1.550(c) for extensions of time in reexamination proceedings.

3. The proceedings herein are for a patent application and the provisions of 37 C.F.R. Section 1.136 apply.

*(complete (a) or (b), as applicable)*

- (a) ☐ Applicant petitions for an extension of time under 37 C.F.R. Section 1.136 (fees: 37 C.F.R. Section 1.17(a)(1)-(4)) for the total number of months checked below:

Extension (months)	Fee for other than <u>small entity</u>	Fee for <u>small entity</u>
<input type="checkbox"/> one month	\$ 110.00	\$ 55.00
<input type="checkbox"/> two months	\$ 410.00	\$ 205.00
<input type="checkbox"/> three months	\$ 930.00	\$ 465.00
<input type="checkbox"/> four months	\$ 1,450.00	\$ 725.00

Fee: \$0.00

If an additional extension of time is required, please consider this a petition therefor.

*(check and complete the next item, if applicable)*

- ☐ An extension for \_\_\_\_\_ months has already been secured. The fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ \_\_\_\_\_

OR

- (b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition for extension of time.

(Amendment Transmittal—page 2 of 4)

**FEE FOR CLAIMS**

4. The fee for claims (37 C.F.R. Section 1.116(b)-(d)) has been calculated as shown below

(Col.1)	(Col. 2)	SMALL ENTITY			OR	OTHER THAN A SMALL ENTITY	
Claims Remaining After Amendment	Highest No. Previously Paid For	Present Extra	Rate	Addit. Fee		Rate	Addit. Fee
			<b>\$9.00</b>	<b>\$0.00</b>		<b>\$18.00</b>	<b>\$0.00</b>
Independent Claims			<b>\$42.00</b>	<b>\$0.00</b>		<b>\$84.00</b>	<b>\$0.00</b>
First Presentation of Multiple Dependent Claim+			<b>\$140.00</b>	<b>\$0.00</b>		<b>\$280.00</b>	<b>\$0.00</b>
						<b>Total Addit. Fee</b>	<b>\$0.00</b>

\* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3,

\*\* If the "Highest No. Previously Paid For" IN THIS SPACE is less than 20, enter "20".

\*\*\* If the "Highest No. Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest No. Previously Paid For" (Total or Indep.) is the highest number found in the appropriate box in Col. 1 of a prior amendment or the number of claims originally filed.

**WARNING:** "After final rejection or action (Section 1.113) amendments may be made canceling claims or complying with any requirement of form which has been made." 37 C.F.R. Section 1.116(a) (emphasis added).

(complete (c) or (d), as applicable)

(c) ☒ No additional fee for claims is required.

OR

(d) ☐ Total additional fee for claims required \$ \_\_\_\_\_.

**FEE PAYMENT**

5. ☐ Attached is a check in the sum of \$ \_\_\_\_\_.

☐ Charge Account No. \_\_\_\_\_ the sum of \$ \_\_\_\_\_.

A duplicate of this transmittal is attached.

(Amendment Transmittal--page 3 of 4)

**FEE DEFICIENCY**

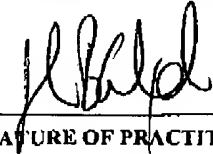
*NOTE: If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO Finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, (1065 O.G. 31-33).*

6. [X] If any additional extension and/or fee is required, charge Account No. 04-1105.

**AND/OR**

- [X] If any additional fee for claims is required, charge Account No. 04-1105.

Date: May 17, 2004

  
\_\_\_\_\_  
SIGNATURE OF PRACTITIONER

John B. Alexander, Ph.D. (Reg. No. 48,399)  
(type or print name of practitioner)

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BOS2\_444946.1

(Amendment Transmittal--page 4 of 4)

**FFICIAL**

Docket No.: 56238 (71526)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****RECEIVED  
CENTRAL FAX CENTER****MAY 17 2004**

APPLICANT: M. Sakanaka, et al. EXAMINER: D. Khare  
SERIAL NO.: 09/913,669 GROUP: 1623  
FILED: August 16, 2001  
FOR: CEREBROVASCULAR REGENERATION/  
RECONSTRUCTION-PROMOTING AGENTS AND  
SECONDARY NERVOUS TISSUE DEGENERATION-  
INHIBITING AGENTS COMPRISING GINSENOSE RB1

Mail Stop: No Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**AMENDMENT AND RESPONSE TO RESTRICTION**

Sir:

Applicants are in receipt of the Office Action dated April 20, 2004 and request reconsideration of the above-identified application in view of the following amendments and remarks. Please amend the above-identified application as follows:

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

**Remarks/Arguments** begin on page 5 of this paper.

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**Amendments To The Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of claims:

1-31. (Cancelled).

32. (Previously Presented) A method for the treatment of diseases caused by injuries to nervous tissues or to the spinal cord, the method comprising the step of administering to a patient a therapeutically effective amount of a pharmaceutical composition comprising a therapeutic agent selected from ginsenoside Rb<sub>1</sub>, its metabolites and salts thereof.

33. (Previously Presented) The method of claim 32, wherein the pharmaceutical composition is capable of suppressing the secondary degeneration of the nervous tissues caused by injuries to the nervous tissues or to the spinal cord.

34. (Previously Presented) The method of claim 33, wherein the secondary degeneration of the nervous tissues is caused by a spinal cord injury.

35. (Previously Presented) The method of claim 32, wherein the therapeutic agent is capable ameliorating paralysis or paraplegia.

36. (Previously Presented) The method of claim 35, wherein the paralysis or paraplegia is caused by a spinal cord injury.

37. (Previously Presented) The method of claim 32 wherein the secondary degeneration of the nervous tissues is caused by a traumatic injury.

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38. (Previously Presented) The method of claim 32, wherein the pharmaceutical composition is capable of suppressing the secondary degeneration of the nervous tissues caused by demyelination.

39. (Previously Presented) The method of claim 38, wherein the pharmaceutical composition is capable of suppressing apoptosis or apoptosis-like cell death of oligodendrocytes.

40. (Previously Presented) The method of claim 32, wherein the pharmaceutical composition is administered intravenously to the patient.

41. (Previously Presented) The method of claim 32, wherein the pharmaceutical composition is administered in a single intravenous infusion or in a continuous intravenous infusion to the patient.

42. (Previously Presented) The method of claim 32, wherein the therapeutically effective amount of the pharmaceutical composition provides a concentration of ginsenoside Rb<sub>1</sub>, its metabolites or salts thereof to the extracellular fluid in lesion at a concentration of 1 ng/ml or less.

43. (Previously Presented) The method of claim 32, wherein the therapeutically effective amount of the pharmaceutical composition provides a concentration of ginsenoside Rb<sub>1</sub>, its metabolites or salts thereof to the extracellular fluid in lesion at a concentration of 1 pg/ml or less.

44. (Previously Presented) The method of claim 32, wherein the therapeutically effective amount of the pharmaceutical composition provides a concentration of ginsenoside Rb<sub>1</sub>, its metabolites or salts thereof to the extracellular fluid in lesion at a concentration of 100 fg/ml or less.



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45. (Cancelled).

46. (Previously Presented) A method for treating trauma or traumatic injuries, the method comprising administering to a patient a therapeutically effective amount of a pharmaceutical composition comprising a therapeutic agent selected from ginsenoside Rb<sub>1</sub>, its metabolites and salts thereof.

47. (Previously Presented) The method of claim 46, wherein the trauma or traumatic injuries are caused by spinal cord injuries, neurotrauma, or head injuries.

48-49. (Cancelled).

50. (Previously Presented) A method for treatment of injuries caused by demyelination, the method comprising administering to a patient a therapeutically effective amount of a pharmaceutical composition comprising a therapeutic agent selected from ginsenoside Rb<sub>1</sub>, its metabolites and salts thereof.

51. (Previously Presented) The method of claim 50, wherein the demyelination is caused by a spinal cord injury.

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**REMARKS**

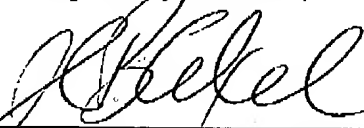
The Applicants appreciate the Examiner's thorough examination of the subject application. Applicants request reconsideration of the subject application based on the following remarks.

Claims 32-44, 46-47, and 50-51 are pending in the application. Claims 1-31, 45, and 48-49 have been cancelled. Applicants expressly reserve the right to pursue the subject matter of the cancelled claims in this or a subsequent application.

In response to the Restriction Requirement, Applicant elects Group I, claims -44, 46-47, and 50-51. The present election is made solely to comply with the Office Action and should not be construed as a surrender of any subject matter of the application. Applicant reserves the right to file divisional application(s) on the non-elected claims.

Although it is not believed that any additional fees are needed to consider this submission, the Examiner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,



Date: May 17, 2004

John B. Alexander (Reg. No. 48,399)  
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